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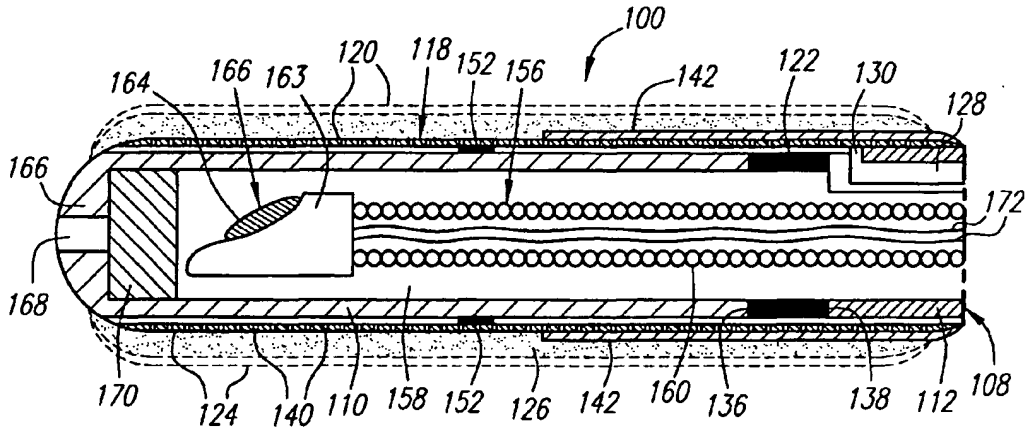

(57) Abstract: A catheter for ablating and imaging tissue includes a porous electrode structure comprising an interior region for receiving a conductive medium, and elongate tube having a distal tube end that extends within the interior region, and an ultrasonic transducer assembly housed within the distal tube end. The porous electrode structure includes an interior region that receives an ionic medium. RF energy can then be ionically transported through the pores within the electrode structure and into the tissue. The distal tube end and porous electrode structure are ultrasonically transparent, allowing the ultrasonic transducer assembly to image therethrough. The ultrasonic transducer assembly is sealed within the distal tubular end and is thereby isolated from the adverse corrosive and thermal effects of the ionic medium.

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ABLATION AND IMAGING CATHETER

FIELD OF THE INVENTION

The present invention relates to systems and methods for visualizing and ablating interior regions of the human body.

BACKGROUND OF THE INVENTION

Physicians make use of catheters today in medical procedures to gain access into interior regions of the body for ablating targeted tissue areas. These procedures, called electrophysiological therapy, are becoming more widespread for treating cardiac rhythm disturbances. It is important for the physician to control carefully and precisely these ablation procedures, especially during procedures that ablate tissue within the heart. During electrophysiological therapy, the physician introduces an ablation catheter through a main vein or artery, typically the femoral vein or artery, into the interior region of the heart that is to be treated. Placement of the ablation catheter within the heart is typically facilitated with the aid of a long introducer or guiding catheter. The physician then further manipulates a steering mechanism to place an ablation electrode carried on the distal tip of the ablation catheter into direct contact with the tissue that is to be ablated. The physician directs radio frequency energy from the ablation electrode through tissue to an indifferent electrode, or another catheter-mounted electrode, to ablate the tissue and form a lesion.

Fluoroscopic imaging is widely used to identify anatomical landmarks within the heart, as well as to locate the position of the ablation electrode relative to the targeted ablation site. It is often difficult, however, to identify these anatomic sites using fluoroscopy. It is also difficult, if not impossible, to use fluoroscopy to ascertain that the desired lesion pattern has been created after ablation. Often, the achievement of desired lesion characteristics must be inferred, based upon measurements of applied ablation power, system impedance, tissue temperature, and ablation time. Furthermore, fluoroscopy cannot readily locate the border zones

between infarcted tissue and normal tissue, where efficacious ablation zones are believed to reside.

Ultrasonic imaging can be used to facilitate the tissue ablation process. After a tissue lesion is created, the ablation catheter can be removed from the body, and an ultrasonic imaging catheter can be inserted through the long introducer or guiding catheter and into the heart to visualize the ablated tissue. Use of ultrasonic imaging during an ablation process, however, is limited. If, after ultrasonic visualization, the characteristics of the tissue lesion are not satisfactory, the ablation catheter must be reinserted into the heart, with the ablation electrode repositioned against the ablated tissue. The catheter exchange, and more significantly, the repositioning of the ablation electrode, can become quite tedious and inefficient. Additionally, since it is often difficult to maneuver both an ablation catheter and an ultrasonic imaging catheter within the heart, ultrasonic imaging is typically accomplished subsequent to the initial tissue lesion creation and, therefore, is typically not used as an aid in initially positioning the ablation electrode relative to the targeted tissue site prior to ablation. Even if the ultrasonic imaging catheter and ablation catheter can be simultaneously located within the heart, ultrasonic imaging of the targeted ablation site is accomplished from a viewpoint different from that of the ablation electrode, making it more difficult to provide accurate location of the ablation electrode relative to the targeted ablation site due to the two-dimensionality of the resulting ultrasonic image.

SUMMARY OF THE INVENTION

The present inventions overcome the afore-described drawbacks of conventional RF ablation catheters and imaging catheters by providing a single catheter having both an RF ablation and an imaging capability.

In accordance with a first aspect of the present inventions, an ablation/imaging catheter includes a porous electrode structure having an interior region for receiving a conductive medium, an elongate tube having a distal tube end that extends within the interior region of the porous electrode structure, and an

ultrasonic transducer assembly housed within the distal tube end. The elongate tube can be composed of either a single tubular element or a plurality of tubular elements axially affixed to one another. The ultrasonic transducer assembly can be comprises of, e.g., a rotatable imaging core or a phased array of transducers.

In the preferred embodiment, the porous electrode structure is filled within an ionic medium and an actuating electrode (e.g., an annular ablation ring mounted to the distal tube end) is placed in communication with the ionic medium, such that RF energy produced by the actuating electrode is ionically conveyed through the medium, out through the pores, and into the surrounding tissue. The electrode structure is composed of a microporous material, thereby preventing significant perfusion of the ionic medium through the electrode structure. Alternatively, the pores of the electrode structure can be larger, allowing the perfusion of the charged ionic medium to the surrounding tissue. The ultrasonic transducer assembly can be composed of either expandable/collapsible material, the expansion and collapsing of which is controlled by the volume of ionic medium, or a semi-rigid or rigid material, which substantially maintains its shape regardless of the volume of the ionic medium. To prevent the ultrasonic transducer assembly from being exposed to the adverse corrosive and thermal effects of the ionic medium, the distal end of the tube in which the ultrasonic transducer assembly resides is sealed from the interior region of the electrode structure.

In accordance with a second aspect of the present inventions, an ablation/imaging catheter comprises an elongate tube having a distal tube end, an imaging element, e.g., an ultrasonic transducer element or optical imaging element, housed within the distal tube end, and an electrode structure mounted to the distal tube end. The imaging element is configured to emit energy through the distal tube end and electrode structure to produce an image of the surrounding tissue. The distal tube end and the electrode structure are substantially transparent to the energy emitted by the imaging element, i.e., the distal tube end and electrode structure contain no elements that would introduce artifacts within the resulting image. In the

preferred embodiment, the electrode structure comprises the afore-described microporous electrode structure, which is free of artifact producing elements.

Other and further objects, features, aspects, and advantages of the present inventions will become better understood with the following detailed description of the accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

The drawings illustrate both the design and utility of preferred embodiments of the present inventions, in which:

Fig. 1 is a plan view of a preferred RF ablation and ultrasonic imaging catheter constructed in accordance with the present inventions, wherein the catheter is shown interfacing with an RF generator, motor drive unit, and ultrasonic signal processor;

Fig. 2 is a plan view of the catheter of Fig. 1, particularly showing an operative distal region, deflectable region, and main region of the catheter;

Fig. 3 is a longitudinal-sectional view taken along the lines 3-3 of Fig. 2;

Fig. 4 is a cross-sectional view taken along the lines 4-4 of Fig. 2;

Fig. 5 is a cross-sectional view taken along the lines 5-5 of Fig. 2;

Fig. 6 is a longitudinal-sectional view taken along the lines 6-6 of Fig. 2;

Fig. 7 is a cross-sectional view taken along the lines 7-7 of Fig. 2;

Fig. 8 is a plan view of the catheter of Fig. 1 positioned within a heart, particularly showing the catheter performing ultrasonic imaging of heart tissue to locate a potential ablation site;

Fig. 9 is a plan view of the catheter of Fig. 1 positioned within the heart, particularly showing the catheter performing ablation of the heart tissue to create a tissue lesion;

Fig. 10 is a plan view of the catheter of Fig. 1 positioned within the heart, particularly showing the catheter performing ultrasonic imaging of a tissue lesion;

Fig. 11 is a longitudinal-sectional view of the distal end of an alternatively preferred RF ablation and ultrasonic imaging catheter constructed in accordance with the present inventions; and

Fig. 12 is a cross-sectional view taken along the lines 12-12 of Fig. 11.

DETAILED DESCRIPTION OF THE DRAWINGS

With reference to Fig. 1, a preferred RF ablation and ultrasonic imaging catheter 100, constructed in accordance with the present inventions, is now described. The catheter 100 provides a physician a single device for therapeutically ablating tissue, such as heart tissue, as well as imaging the tissue prior to, concurrently, or subsequent to the ablation process. In this regard, the catheter 100 can be connected to an RF generator 200, such as that described in Jackson et al., U.S. Patent No. 5,383,874, the specification of which is fully and expressly incorporated herein by reference. The RF generator 200 provides the catheter 100 with a source of RF ablation energy. Thus, when operated, the RF generator 200 allows the physician to ablate tissue, such as heart tissue, in a controlled manner, resulting in a tissue lesion with the desired characteristics. The catheter 100 can also be connected to a motor drive unit 300 and an ultrasonic signal processor 400, which when operated, allows the physician to obtain 360-degree two-dimensional ultrasonic images of the target tissue site, prior to, during and subsequent to the ablation process.

The catheter 100 can be functionally divided into four regions: the operative distal catheter region 102, a deflectable catheter region 104, a main catheter region 106, and an interfacing proximal catheter region 107. The distal catheter region 102 represents the active component that provides the ultrasonic and ablative capability to the catheter 100. The deflectable catheter region 104 provides steering capability to the catheter 100, and particularly, provides an efficient and effective means of manipulating the distal catheter region 102. The main catheter region 106 provides the catheter 100 with the required length to deliver the distal catheter region 102 from the insertion point of the patient (typically, the femoral vein or artery) to the targeted tissue site. Lastly, the proximal catheter region 107, which includes a handle assembly 132 and a proximal adapter 174, provides interfacing capability between the catheter 100 and other instruments, such as the RF generator 200, motor drive unit 300, and signal processor 400, as well as a means for introducing and removing fluids into and out of the catheter 100. The construction and

operation of the distal, deflectable, main, and proximal catheter regions 102, 104, 106, and 107 will be described in further detail below.

Referring to Fig. 2, the catheter 100 includes a catheter body 108, which carries a differing number of functional lumens and has a varying flexibility along its length. In this regard, the catheter body 108 is composed of several extruded tubular elements affixed together in an axial arrangement. In particular, the catheter body 108 includes first and second tubular elements 110 and 112, which, in combination, form the structure of the distal catheter region 102; a third tubular element 114, which forms the structure of the deflectable catheter region 104; and a fourth tubular element 116, which forms the structure of the main catheter region 106. It should be noted, however, that the catheter body 108 can include any number of tubular elements required to provide the desired functionality to the catheter 100.

The tubular elements 110, 112, 114, and 116 are composed of a flexible and biocompatible material. In the illustrated embodiment, the second, third, and fourth tubular elements 112, 114, and 116 can be composed of a non-conductive thermoplastic elastomer, such as polyurethane. Preferably, the first tubular element 110 is composed of a more ultrasonically transparent material, such as polyethylene. As will be described in further detail below, the tubular elements 110, 112, 114 and 116 are suitably bonded together by means, such as adhesive or thermal bonding, to integrally form the catheter body 108. Additionally, heat shrink tubing (not shown) can be shrunk over the catheter body 108 to provide a more integral catheter structure. The catheter body 108 can be variously sized, assuming the selected size allows the catheter body 108 to be routed through the vasculature of the patient to the targeted tissue site. By way of non-limiting example, a 9F catheter body 108 having a length of 100 cm will allow the catheter distal region 102 to be delivered to the interior of the heart via the femoral vein or artery.

Referring to Figs. 3 and 4, the catheter distal region 102 is now described in detail. The catheter distal region 102 carries an ablation assembly 118, which includes an expandable-collapsible electrode body 120 and an actuating electrode, and particularly, an ablation ring 122. The electrode body 120 is suitably mounted

to the catheter body 108, such that an interior region 124 of the electrode body 120 is in communication with substantially the entire exterior surface of the first tubular element 110, and at least a portion of the exterior surface of the second tubular element 112. As will be described in further detail below, to prevent interference with the imaging capability of the catheter 100, the electrode body 120 is composed of an ultrasonically transparent thermoplastic or elastomeric material, such as regenerated cellulose, polysulfone, silicone, polyurethane, santoprene, C-Flex®, Kraton®, Latex, Neoprene, or other suitable materials.

The geometry of the electrode body 120 can be altered between a collapsed geometry and an enlarged, expanded geometry (represented by broken line). In the illustrated embodiment, an electrically conductive medium 126, under pressure, is used to fill the interior region 124, and thus, inflate and maintain the electrode body 120 in the expanded geometry. The electrically conductive medium 126 is conveyed to and from the interior region 124 of the electrode body 120 via an inflation lumen 128 formed through the catheter body 108, and in particular, the second, third and fourth tubular elements 112 (shown in Figs. 5-7). The inflation lumen 128 is in fluid communication with the interior region 124 of the electrode body 120 via an infusion hole 130 formed through the wall of the catheter body 108, and specifically, the wall of the second tubular element 112.

Referring further to Fig. 1, the inflation lumen 128 terminates proximally in the handle assembly 132, and particularly within a handle 133 of the handle assembly 132. The handle assembly 132 further includes an inflation port 134, which is in fluid communication with the inflation lumen 128 within the handle 133. Thus, electrically conductive medium 126 (hypertonic solution and a mixture of ionic/non-ionic contrast, or an ionic contrast alone) can be introduced into, or removed from, the inflation port 128, providing a convenient means of selectively inflating and deflating the electrode body 120.

In alternative embodiments, the electrode body 120 of the ablation assembly 118 is formed of a porous semi-rigid or rigid material, such as regenerated celluose having a suitable thickness, e.g., 2-3 mils. In this case, the electrode body 120 is not

readily expandable and collapsible, but is naturally formed into a semi-expanded or expanded geometry having a dimension that is suitable for passage through the patient's vasculature and into the interior of the heart.

Referring specifically to Figs. 3 and 4, the ablation ring 122 is circumferentially located between the first tubular element 110 and the second tubular element 112. In particular, a proximal edge 136 of the first tubular element 110, and a distal edge 138 of the second tubular element 112, are affixed to the opposite edges of the ablation ring 122 by suitable means, such as adhesive or thermal bonding, providing an integral connection between the first tubular element 110 and the second tubular element 112. The ablation ring 122 provides RF energy to the electrode body 120 via the electrically conductive medium 126. In this regard, the ablation ring 122 is preferably made of a material having both a relatively high electrical conductivity and a relatively high thermal conductivity, such as gold, platinum, or platinum/iridium, and is in communication with the interior region 124 of the electrode body 120.

It should be noted that the ring-like structure of the ablation ring 122 provides a relatively large circumferential exterior surface of the ablation ring 122 to be in communication with the interior region 124 of the electrode body 120, providing an efficient means of energizing the electrically conductive medium 126. Although, in the illustrated embodiment, the actuating electrode advantageously takes the form of a ring, the actuating electrode can take the form of any suitable structure that can be placed in contact with the electrically conductive medium 126. The length of the ablation ring 122 can be accordingly varied to increase or decrease the amount of RF energy delivered to the electrically conductive medium 126. The location of the ablation ring 122 can also be varied, but should be positioned, so that the imaging capability of the catheter 100 is not interfered with.

The electrically conductive medium 126 is composed of an electrically conductive liquid, which establishes an electrically conductive path from the ablation ring 122 to the surface of the electrode body 120. Preferably, the electrically conductive medium 126 possesses a low resistivity to decrease ohmic

losses and, thus, ohmic heating effects, within the electrode body 120. The composition of the electrically conductive medium 126 can vary. In the illustrated embodiment, the electrically conductive medium 126 comprises a hypertonic saline solution, having a sodium chloride concentration at or near saturation, which is about 23% weight by volume. Alternatively, the electrically conductive medium 126 comprises a mixture of saline and ionic/non-ionic contrast, or an ionic contrast alone.

Although the material in which the electrode body 120 is composed of is electrically non-conductive, the electrode body 120 includes pores 140 on at least a portion of its surface. The porous structure of the electrode body 120 acts as the energy-emitting surface of the electrode body 120, establishing ionic transport of RF energy from the ablation ring 122, through the electrically conductive medium 126, through the pores 140, and into the tissue outside of the electrode body 120, thereby creating a lesion.

The geometry of the energy-emitting surface of the electrode body 120 can be customized to more efficiently produce desired lesion characteristics. In particular, the delivery of RF energy from the ablation ring 122 to the electrode body 120 can be concentrated in certain regions of the electrode body 120 by masking the pores 140 of the electrode body 120. For example, in the illustrated embodiment, a mask 142, composed of a non-porous material, such as polyurethane, is bonded (e.g., by lamination or deposition) to a portion of the electrode body 120, and particularly, the proximal region of the electrode body 120. In this manner, the RF energy delivered to the electrode body 120 is concentrated in the distal region of the electrode body 120, which may be particularly useful in ablation within the pulmonary vein.

The electrical resistivity of the electrode body 120 has a significant influence on the tissue lesion geometry and controllability. Ablation with a low-resistivity electrode body 120 requires more RF power and results in deeper lesions. On the other hand, ablation with a high-resistivity electrode body 120 generates more uniform heating, therefore improving the controllability of the lesion. Generally

speaking, lower resistivity values for the electrode body 120 (below about 500 ohm-cm), result in deeper lesion geometries, while higher resistivity values for the electrode body 120 (above about 500 ohm-cm), result in shallower lesion geometries. Preferably, the electrical resistivity of the electrode body 120 falls within a range between 150 ohm-cm to 2000 ohm-cm.

The electrical resistivity of the electrode body 120 can be controlled by specifying the pore size of the material, the porosity of the material (space on the body that does not contain material), and the water absorption characteristics (hydrophilic versus hydrophobic) of the material. In general, the greater the pore size and porosity, the lesser the resistivity of the electrode body 120. In contrast, the lesser the pore size and porosity, the greater the resistivity of the electrode body 120. Preferably, the size of the pores 140 is selected, such that little or no liquid perfusion through the pores 140 results, assuming a maximum liquid pressure within the interior region 124 of the electrode body 120.

In general, hydrophillic materials possess a greater capacity to provide ionic transfer of radiofrequency energy without significant perfusion of liquid through the electrode body 120 than do hydrophobic materials. Additionally, hydrophilic material generally has less friction than hydrophobic material, facilitating routing of the catheter 100 through the vasculature of the patient. In this regard, the catheter body 108, including the mask 142, is preferably composed of a hydrophillic material. Further details concerning the manufacture of the electrode body 120, including the specification of the pore size, porosity, and water absorption characteristics of the material, are disclosed in Swanson et al., U.S. Patent No. 5,797,903, the specification of which is fully and expressly incorporated herein by reference.

Referring further to Fig. 1, delivery of RF energy to the ablation assembly 118 is controlled by the RF generator 200, as briefly discussed above. The RF generator 200 includes an RF source 202 for generating the RF energy, and a controller 204, which controls the amplitude of, and time during, which the RF source 202 outputs RF energy. The RF generator 200 is electrically coupled to the ablation assembly

118 of the catheter 100 via the handle assembly 132. Specifically, the handle assembly 132 includes a cable 144 and a plug 146 associated therewith. The plug 146 mates with a socket 206 located on the RF generator 200, and which is electrically coupled to the RF source 202 and controller 204.

Referring further to Figs. 5 and 7, ablation wires 148 are routed through ablation wire lumens 150 formed within the catheter body 108, and specifically, through the second, third, and fourth tubular elements 112, 114, and 116. The distal ends of the ablation wires 148 are suitably connected to the ablation ring 122, and the proximal ends of the ablation wires 148 are suitably connected to the handle 133 in communication with the 144 (connections not shown).

Thus, mating of the plug 146 with the socket 206 of the RF generator 200 provides an electrical connection between the RF source 202 and the ablation ring 122. Operation of the RF generator 200 provides RF energy to the ablation ring 122, which in turn is ionically transferred through the electrically conductive medium 126 and out through the pores 140 of the electrode body 120 into the targeted tissue region.

Referring specifically to Fig. 3, to facilitate control of the RF energy delivery, the catheter 100 further includes one or more temperature sensing elements 152 carried by the electrode body 120. The temperature sensing elements 152 can take the form of thermistors, thermocouples, or the equivalent. The sensing elements 152 are in thermal conductive contact with the electrode body 120 to sense thermal conditions outside of the electrode body 120. In the illustrated embodiment, the temperature sensing elements 152 are located within the interior region 124 of the electrode body 120. The temperature sensing elements 152, however, can be mounted on the outside of the electrode body 120 in alternative embodiments.

Referring further to Figs. 1, 5, and 7, the temperature sensing elements 152 are electrically coupled via signal wires 154 (connections not shown), which are routed through the ablation wire lumens 150 of the catheter body 108, terminating in the handle 133. The temperature sensed by the temperature sensing elements 152 are processed by the controller 204, which, based upon this temperature input,

adjusts the time and power level of radio frequency energy delivered from the RF source 202 to the ablation assembly 118 to achieve the desired lesion patterns and other ablation objectives. Various ways of attaching temperature sensing elements to an electrode body 120 are described in Whayne et al., U.S. Patent No. 5,853,411, the specification of which is fully and expressly incorporated herein by reference.

Referring specifically to Figs. 3 and 4, the catheter 100 includes an ultrasonic imaging core 156, which is rotatably disposed within an imaging lumen 158 formed through the center of the catheter body 108. The imaging core 156 includes a drive cable 160 with a distally mounted ultrasonic transducer assembly 162. The drive cable 160 is preferably designed, such that it possesses a high torsional stiffness and a low bending stiffness. For example, the drive cable 160 can be made of two counterwound layers of multifilar coils, which are fabricated using techniques disclosed in Crowley et al., U.S. Patent No. 4,951,677, and fully and expressly incorporated herein by reference.

The ultrasonic transducer assembly 162 includes a housing 163 and an ultrasonic transducer 164 mounted within the housing 163. The ultrasonic transducer 164 is suitably mounted within the housing 163, and is composed of a piezoelectric element, matching layer, and conductive backing material (not shown). The ultrasonic transducer assembly 162 and drive cable 160, i.e., the ultrasonic imaging core 156, rotate as an integral unit. Electrical signals are transmitted to and received from the ultrasonic transducer 164 via signal wires 172, which are suitably connected to the piezoelectric element of the ultrasonic transducer 164, and routed through the drive cable 160.

The ultrasonic transducer 164 emits and receives ultrasonic energy as it rotates within the distal end of the imaging lumen 158. As briefly described above, the first tubular element 110 and electrode body 120 are composed of an ultrasonically transparent material, and thus, in combination, form an acoustic window through which ultrasonic energy can pass to and from the ultrasonic transducer 164 without substantial attenuation. The first tubular element 110 has a tip 166 that is closed with the exception of an orifice 168, which allows for the distal

introduction of an imaging medium 126 into the imaging lumen 158. In the illustrated embodiment, the imaging medium 126 is composed of a 0.9% concentrated saline solution. To prevent leakage of the imaging medium 126 from the imaging lumen 158 out through the orifice 168, the catheter 100 further includes a pierceable septum 170 immediately proximal to the tip 166 of the first tubular element 110 to seal the orifice 168.

It should be noted that the first tubular element 110 thermally and chemically isolates the inflation lumen 128 from the interior region 124 of the electrode body 120. In this manner, the electrically conductive medium 126 within the interior region 124 of the electrode body 120 does not come into contact with the imaging core 156, which might otherwise subject the imaging core 156 to possible corrosion and adverse thermal effects caused by the hypertonic characteristics of the electrically conductive medium 126 and the ionic energization of the electrically conductive medium 126 during the ablation process.

With further reference to Fig. 1, the proximal adapter 174 provides a suitable interface between the imaging core 156 and the motor drive unit 300 and signal processor 400. Specifically, the imaging lumen 158, drive cable 160, and signal wires 172 extend through the handle 133 and a proximal cable 176, terminating in the proximal adapter 174. The proximal adapter 174 mates with a hub 302 of the motor drive unit 300, which, as will be described in further detail below, allows the motor drive unit 300 and signal processor 400 to interact with the imaging core 156. To provide a suitable interface between the signal wires 172 in the rotatable drive cable 160 and the fixed motor drive unit 300 and signal processor 400, the proximal adapter 174 includes an inductive coupler (not shown).

The proximal adapter 174 also provides a means for flushing the imaging lumen 158. Specifically, the proximal adapter 174 includes a flush port 178, which is in fluid communication with the imaging lumen 158. Thus, when the imaging medium is distally introduced into the imaging lumen 158, the flush port 178 can be opened to advantageously allow air, the presence of which may otherwise adversely

affect the ultrasonic imaging capability of the catheter 100, to escape the imaging lumen 158.

The motor drive unit 300 provides the means for rotating the imaging core 156. In this regard, the motor drive unit 300 includes a motor 304 and a rotatable drive shaft 306 associated therewith, which engages the proximal end of the drive cable 160 of the imaging core 156 when the proximal adapter 174 is mated with the hub 302. The signal processor 400 provides the means for electrically exciting the rotating ultrasonic transducer 164, as well as interpreting and transforming the electrical signals received from the ultrasonic transducer 164 into user discernible imaging information. In this regard, the signal wires 172 of the imaging core 156 are coupled transparently through the motor drive unit 300 to the signal processor 400. The signal processor 400 includes a transceiver 402, which transmits electrical pulses to the imaging core 156 and receives return electrical pulses from the imaging core 156. In the illustrated embodiment, the ultrasonic transducer 164 is designed to have a center frequency at a usable range between 2 to 44 MHz, and thus, the transceiver 402 is configured to deliver electrical pulses to the transducer 402 at between 2 to 44 MHz. The signal processor 400 further includes an imaging data processor 404, which receives the return electrical pulses from the transceiver 402 as imaging data, and processes the imaging data for display on a display unit 406.

Thus, simultaneous operation of the motor drive unit 300 and signal processor 400 generates 360-degree two-dimensional ultrasonic images of the targeted tissue region. In particular, operation of the motor drive unit 300 rotates the drive cable 160, and thus the ultrasonic transducer 164, at a high rate of speed. While the ultrasonic transducer 164 is rotating, the transceiver 402 transmits an electrical pulse to the ultrasonic transducer 164 via the signal wires 172. The electrically excited ultrasonic transducer 164 emits ultrasonic energy, which is transmitted to the first tubular element 110 and electrode body 120 (both of which are ultrasonically transparent) into the tissue. A portion of the ultrasonic energy is, in turn, reflected off of the tissue, back through the first tubular element 110 and electrode body 120, and into the ultrasonic transducer 164. This reflected ultrasonic energy produces a return

electrical signal in the ultrasonic transducer 164, which is transmitted back to the transceiver 402 via the signal wires 172, as imaging data. The transceiver 402 repeatedly transmits electrical signals to, and receives return electrical signals from, the rotating ultrasonic transducer 164 to obtain further imaging data. This accumulated imaging data is then processed by the processor 404, and displayed on the display unit 406 as a 360-degree two-dimensional image of the tissue for visual interpretation by the physician.

To provide a more effective means of placing the electrode body 120 adjacent the targeted tissue region, the catheter 100 has a steering capability. Referring to Figs. 6 and 7, the catheter body 108 includes a steering lumen 180 and a steering wire 182 slidably disposed therein. The steering lumen 180 terminates distally at an anchor ring 184, which is circumferentially disposed between the second tubular element 112 and the third tubular element 114. In particular, a proximal edge 186 of the second tubular element 112 and a distal edge 188 of the third tubular element 114 are affixed to the opposite edges of the anchor ring 184 by suitable means, such as adhesive or thermal bonding, providing an integral connection between the second tubular element 112 and the third tubular element 114. The distal end of the steering wire 182 is suitably mounted to the anchor ring 184, such as by welding.

Referring further to Fig. 1, the proximal end of the steering wire 182 is suitably mounted within the handle 133 (connection not shown). The handle assembly 132 further includes a collar 190, which moves longitudinally relative to the handle 133. The collar 190 is mounted to the proximal end of the catheter body 108, and particularly, the proximal end of the fourth tubular element 116. Distal movement of the collar 190 relative to the handle 133 (in the direction indicated by the arrow 192), causes the steering wire 182 to move proximally within the steering lumen 180 relative to the catheter body 108, which, in turn, tensions the steering wire 182, thus pulling the anchor ring 184 and bending the catheter deflectable region 104 into an arc (shown by broken lines). On the contrary, proximal movement of the collar 190 relative to the handle 133 (in the direction indicated by the arrow 194), causes the steering wire 182 to move distally within the steering

lumen 180 relative to the catheter body 108, which, in turn, relaxes the steering wire 182, allowing the resiliency of the third tubular element 114 to place the catheter deflectable region 104 of the catheter 100 back into a rectilinear configuration.

Referring specifically to Figs. 6 and 7, the steering lumen 180 is lined with a semi-rigid structure, such as a metallic coil 196, to provide the desired resiliency and arc to the third tubular element 114, and to prevent the third tubular element 114 from kinking or twisting. The fourth tubular element 116 is suitably affixed to the third tubular element 114 by means, such as adhesive or thermal bonding. To provide axial and rotational rigidity to the main region 106 (shown in Figs. 1 and 2) of the catheter 100, the fourth tubular element 116 is extruded with metallic braiding 198. In this manner, the catheter 100 can be readily routed through the tortuous vasculature of the patient without kinking or twisting.

With reference to Figs. 8-10, operation of the catheter 100 to create a lesion at a targeted tissue ablation site 502 within a heart 500, will now be described. For the purposes of brevity in explanation, it is assumed that a long introducer 504 has been previously routed through the patient's vasculature, and into the heart chamber, with the targeted tissue ablation site 502. It is also assumed that a mapping catheter has been introduced through the long introducer or guide catheter 504 and used to identify a potential ablation site as the targeted tissue ablation site 502 relative to anatomical landmarks within the heart 500. A variety of diagnostic mapping techniques can be employed to accomplish this objective. Further details concerning the use of a mapping catheter to identify potential ablation sites within the heart are set forth in Greenspon et al., U.S. Patent No 5,954,661, the specification of which is fully and expressly incorporated herein by reference.

Prior to introduction of the RF ablation and ultrasonic imaging catheter 100 through the long introducer or guide catheter 504, the imaging medium, i.e., 0.9% saline solution, is injected through the orifice 168 and septum 170 via a syringe-needle into the imaging lumen 158 (see Fig. 3). The physician can flush out any air or bubbles trapped in the imaging lumen 158 by opening the flush port 178 located on the proximal adapter 174 (see Fig. 1).

Referring further to Fig. 1, the plug 146 and proximal adapter 174 leading from the handle 133 of the catheter 100 is then mated with the socket 206 of the RF generator 200, and the hub 302 of the motor drive unit 300, respectively. After the mapping catheter is removed from the long introducer 504, the physician introduces the RF ablation and ultrasonic imaging catheter 100 through the long introducer 504 and into the heart 500. Once the catheter distal region 102 is located within the heart 500, the physician can inflate the electrode body 120 by introducing, under pressure, the electrically conductive medium 126 through the inflation port 134 located on the handle 133. Of course, if the electrode body 120 is formed of a semi-rigid or rigid material, the electrically conductive medium 126 does not act to inflate the electrode body 120, but rather, acts merely to establish an electrically conductive path from the ablation ring 122 to the surface of the electrode body 120.

The physician can then operate the motor drive unit 300 and signal processor 400 to ultrasonically image the interior of the heart 500, including the targeted tissue ablation site 502 (Fig. 8), which appears on the display unit 406 of the signal processor 400 (shown in Fig. 1) as a 360-degree two-dimensional image of the heart. While viewing the image on the display unit 406, the physician can identify anatomical landmarks within the heart 500, including the atrio-ventricular annulus, ostium of the pulmonary vein, isthmus between the interior vena cava and tricuspid valve, etc., and manipulate the catheter 100 until the catheter distal region 102 is adjacent the targeted tissue ablation site 502 (shown in phantom) (Fig. 9). The physician can operate the collar 190 on the handle assembly 132 (shown in Fig. 1) to aid in placing the catheter distal region 102 in firm contact with the targeted tissue ablation site 502.

Once the catheter distal region 102 is in contact with the targeted tissue ablation site 502, the physician operates the RF generator 200 to transmit RF energy from the electrode body 120 into the targeted tissue ablation site 502 to create a lesion 506 with the desired characteristics. The physician, simultaneous with, or subsequent to, the ablation process, operates the motor drive unit 300 and signal processor 400 to ultrasonically image the lesion 506, allowing the physician to

monitor the progress of the ablation process by viewing the ultrasonic image of the lesion 506 on the display unit 406 (Fig. 10). This may include determining the lesion depth and/or detecting coagulum, or thrombus formation during ablation. If the physician desires to change the geometric characteristics of the lesion 506 by making it larger, or if further lesions need to be created, the RF generator 200, motor drive unit 300, and signal processor 400 can again be operated to further ablate and image the tissue.

Thus, because the electrode body 120 is ultrasonically transparent, the ultrasonic transducer 164 and electrode body 120 can not only be advantageously located on a single vehicle, but can also occupy virtually the same space, thus obviating the need to exchange catheters and provide a more accurate and efficient means of monitoring the ablation process.

Once the ablation process is completed, the physician can then deflate the electrode body 120 by removing the electrically conductive medium 126 out through the inflation port 134. The physician can then remove the catheter 100 and long introducer 504 from the patient's vasculature. In the case of an electrode body 120 that is formed of a semi-rigid or rigid material, the fixed profile of the electrode body 120 is sufficiently small enough to allow the physician to remove the catheter 100 from the patient's vasculature.

With reference to Figs. 11 and 12, an alternative preferred RF ablation and ultrasonic imaging catheter 600, constructed in accordance with the present inventions, is now described. Like the catheter 100, the catheter 600 provides a physician a single device for therapeutically ablating tissue, such as heart tissue, as well as imaging the tissue prior to, concurrently, or subsequent to the ablation process. To the extent that the features of the catheter 600 are the same as those of the catheter 100, identical reference numbers have been assigned.

The catheter 600 differs from the catheter 100 in that ultrasonic imaging is accomplished through the use of a phased array of ultrasonic transducers 602, which is formed between a backing material 604 and the tubular element 110. The ultrasonic transducer array 602 is shown arranged in a linear circumferential pattern

about the longitudinal axis of the catheter 600 (see Fig. 12). The ultrasonic transducer array 602 can, however, be arranged in other patterns. For example, the ultrasonic transducer array 602 can be arranged in a two-dimensional circumferential pattern about the longitudinal axis of the catheter 600, or arranged in a linear pattern along the longitudinal axis of the catheter 600. To provide electrical pulses to and from the ultrasonic transducer array 602, signal wires 608 extend distally from the ultrasonic transducer array 602 through the catheter body 606, terminating at a controller (not shown). For example, the signal wires 608 can be bundled together and routed through the main lumen of the catheter 600,

The signal processor (not shown) transmits electrical pulses to the ultrasonic transducer array 602 via the signal wires 608. The electrically excited ultrasonic transducer array 602 emits ultrasonic energy, which is transmitted to the first tubular element 110 and electrode body 120 (both of which are ultrasonically transparent) into the tissue. A portion of the ultrasonic energy is, in turn, reflected off of the tissue, back through the first tubular element 110 and electrode body 120, and into the ultrasonic transducer array 602. This reflected ultrasonic energy produces a return electrical signal in the ultrasonic transducer array 602, which is transmitted back to the signal processor via the signal wires 608, as imaging data. As is well known in the art, the signal processor controls the amplitude and phase difference of the electrical pulses transmitted to the ultrasonic transducer array 602 and processes the return electrical pulses in a manner that allows the physician to obtain 360-degree two-dimensional ultrasonic images of the target tissue site. To effect ablation and imaging of the tissue, the catheter 600 can be operated in much the same manner as that described with respect to the catheter 100, with the exception that the absence of a rotatable imaging core obviates the need for a drive unit.

Phased array ultrasonic transducer technology is well known in the art. Further details regarding the arrangement and manufacture of phased ultrasonic transducer arrays for the purposes of imaging are described in U.S. Patent No. 5,848,969 to Panescu et al., U.S. Patent No. 5,938,615 to Eberle et al., and U.S. Patent No. 4,841,977, all fully and expressly incorporated herein by reference.

While preferred methods and embodiments have been shown and described, it will be apparent to one of ordinary skill in the art that numerous alterations may be made without departing from the spirit or scope of the invention. Therefore, the invention is not to be limited except in accordance with the following claims.

What is Claimed is:

1. An ablation/imaging catheter, comprising:

an elongate tube having a distal tube end that extends within the interior region;

a porous electrode structure mounted to the distal tube end and comprising an interior region for receiving a conductive medium; and

an ultrasonic transducer assembly housed within the distal tube end.

2. The catheter of claim 1, wherein the ultrasonic transducer assembly comprises an ultrasonic imaging core.

3. The catheter of claim 1, wherein the ultrasonic transducer assembly comprises a phased array of ultrasonic transducers.

4. The catheter of claim 1, further comprising an actuating electrode in communication with the interior region.

5. The catheter of claim 4, wherein the actuating electrode is an annular ablation ring mounted to the distal tube end.

6. The catheter of claim 1, wherein the porous structure is microporous.

7. The catheter of claim 1, wherein the porous structure is inflatable.

8. The catheter of claim 1, wherein the porous structure is formed of a semi-rigid or rigid material.

9. The catheter of claim 1, wherein a portion of the porous structure is masked.

10. The catheter of claim 1, wherein the porous structure comprises regenerated cellulose.

11. The catheter of claim 1, wherein the distal tube end seals the ultrasonic transducer assembly from the interior region.

12. The catheter of claim 1, further comprising a steering wire mounted to the distal tube end.

13. The catheter of claim 1, wherein the elongate tube is formed from a plurality of axially arranged tubular elements.

14. An ablation/imaging catheter, comprising:
an elongate tube having a distal tube end;
an imaging element housed within the distal tube end; and
an electrode structure mounted to the distal tube end;
wherein the imaging element is configured to emit energy through the distal tube end and electrode structure to produce an image, and the distal tube end and electrode structure are substantially transparent to the imaging energy.

15. The catheter of claim 14, wherein the imaging element comprises an ultrasonic transducer.

16. The catheter of claim 14, wherein the imaging element comprises an ultrasonic imaging core.

17. The catheter of claim 14, wherein the electrode structure comprises a porous electrode structure having an interior region through which the distal tube end extends.

18. The catheter of claim 17, wherein the tubular element seals the imaging element from the interior region.

19. The catheter of claim 17, wherein the porous electrode structure is microporous.

20. The catheter of claim 17, wherein the porous structure is inflatable.

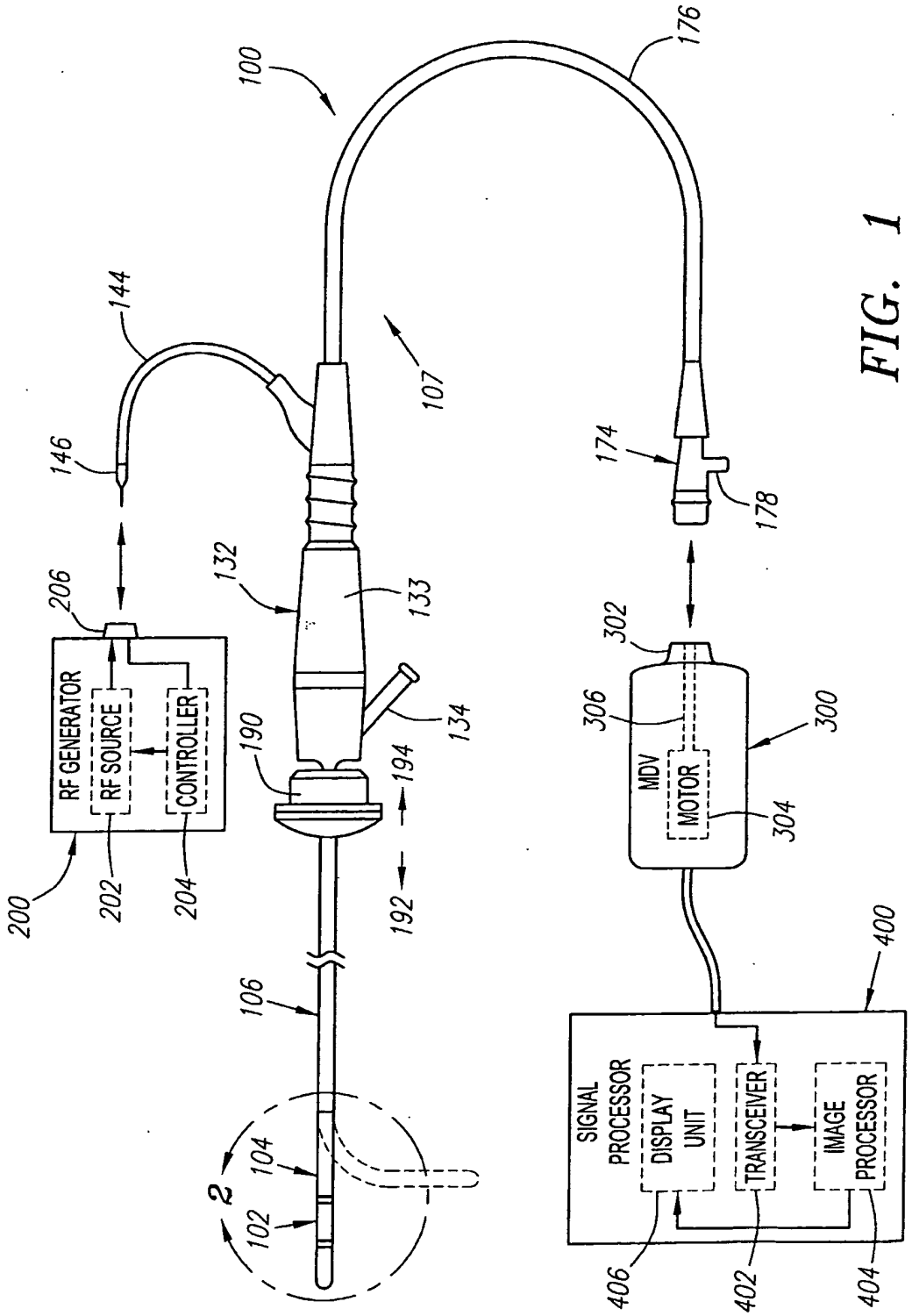
100
176
144
146
107
174
178
206
132
133
302
RF GENERATOR
RF SOURCE
CONTROLLER
190
134
194
306
MDV
MOTOR
300
304
200
202
204
192
400
106
SIGNAL PROCESSOR
DISPLAY UNIT
TRANSCEIVER
IMAGE PROCESSOR
104
2
102
406
402
404

FIG. 1

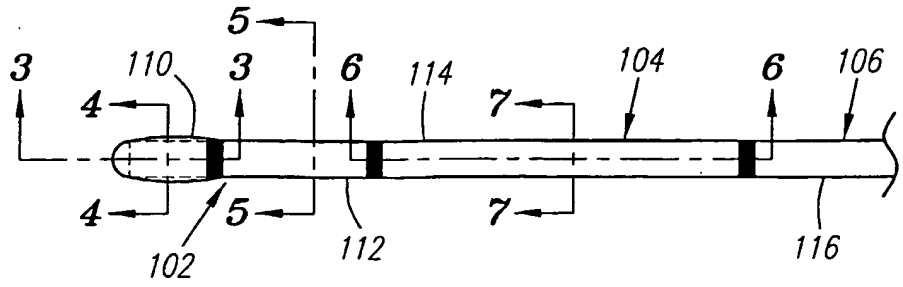

FIG. 2

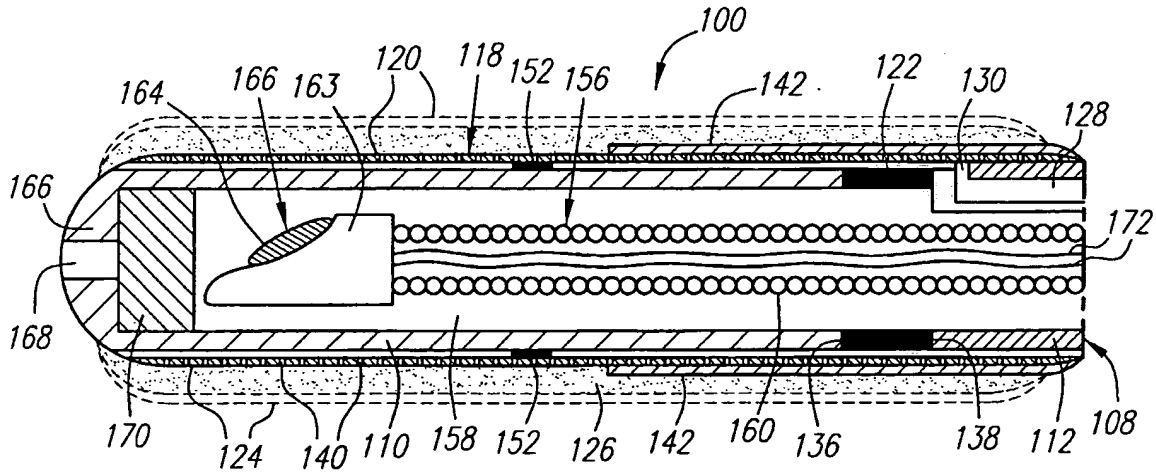

FIG. 3

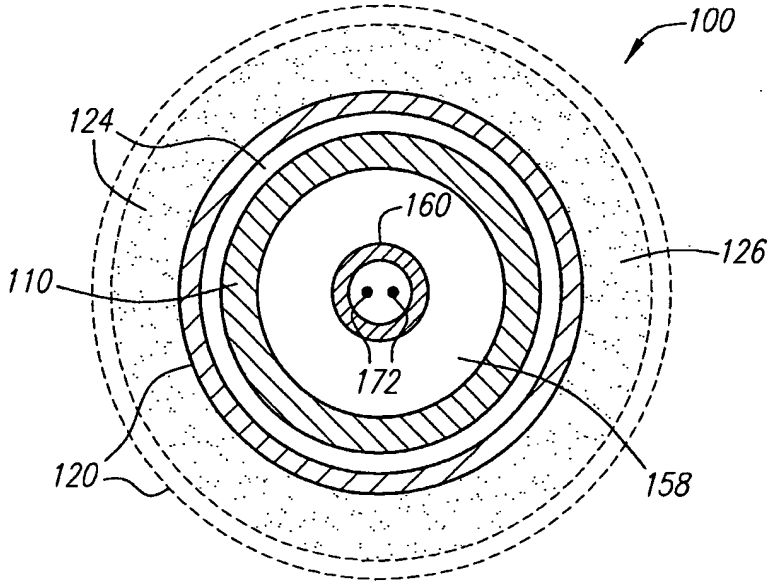

FIG. 4

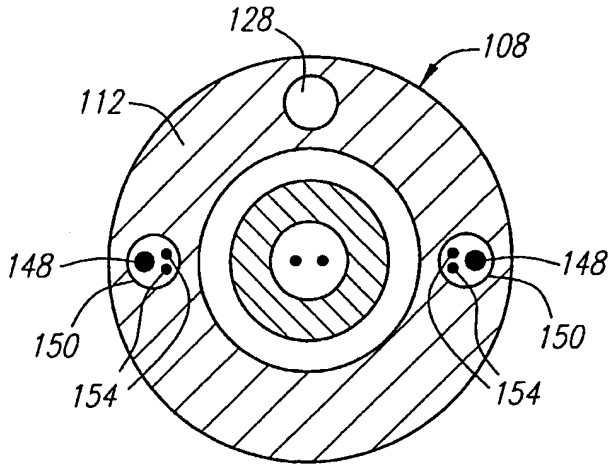

FIG. 5

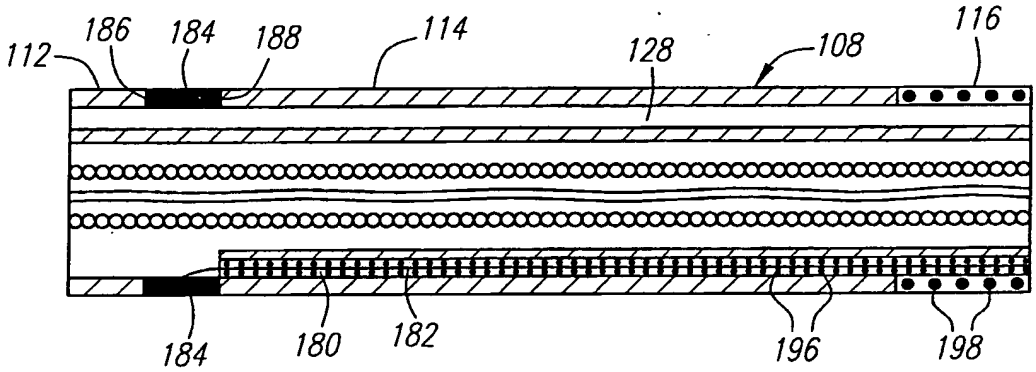

FIG. 6

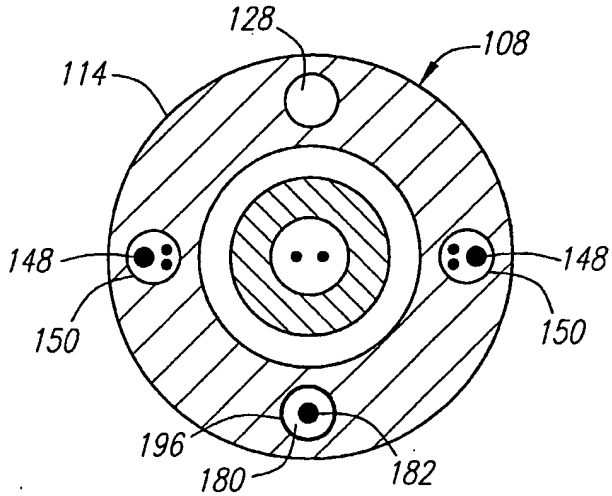

FIG. 7

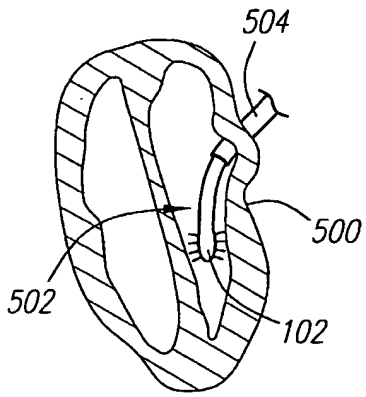

FIG. 8

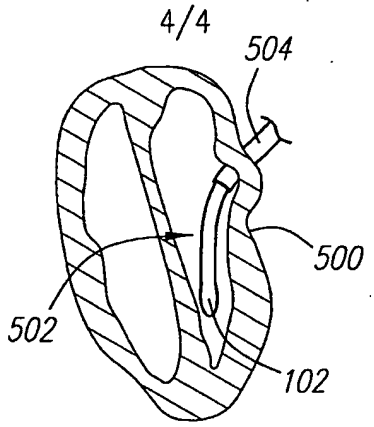

FIG. 9

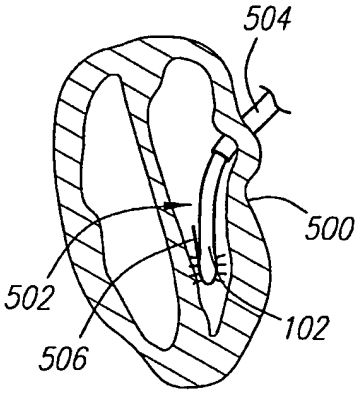

FIG. 10

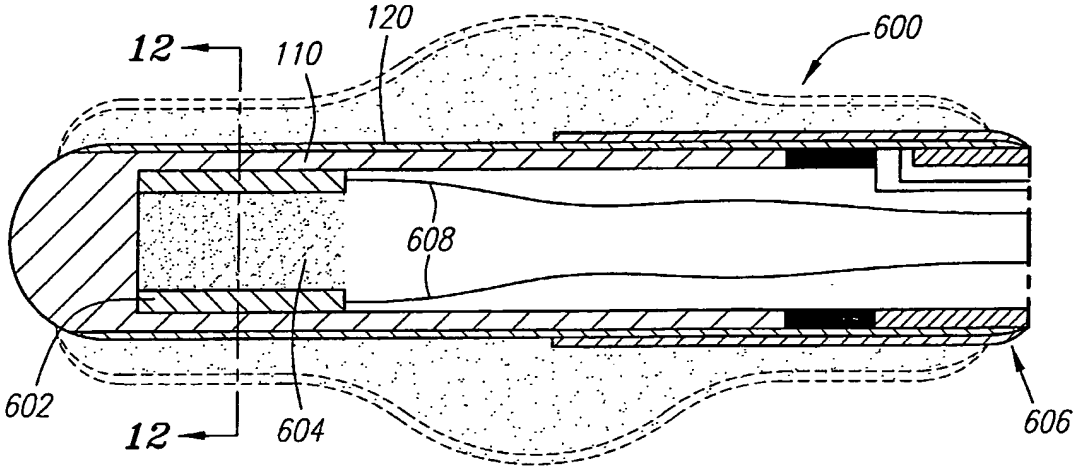

FIG. 11

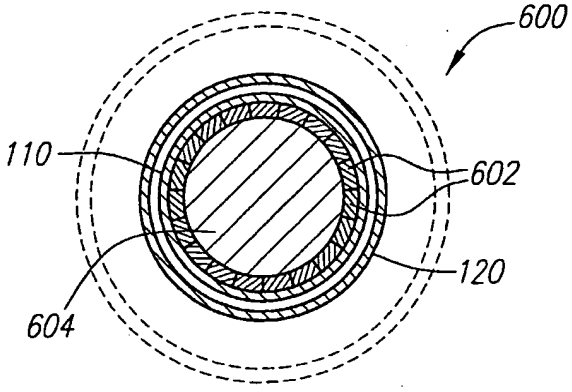

FIG. 12

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(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
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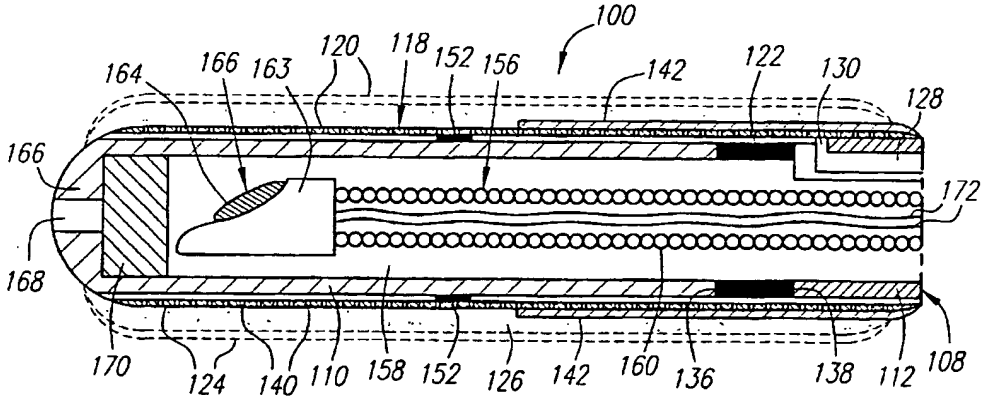
(88) Date of publication of the international search report:
21 February 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ABLATION AND IMAGING CATHETER



(57) Abstract: A catheter for ablating and imaging tissue includes a porous electrode structure comprising an interior region for receiving a conductive medium, and elongate tube having a distal tube end that extends within the interior region, and an ultrasonic transducer assembly housed within the distal tube end. The porous electrode structure includes an interior region that receives an ionic medium. RF energy can then be ionically transported through the pores within the electrode structure and into the tissue. The distal tube end and porous electrode structure are ultrasonically transparent, allowing the ultrasonic transducer assembly to image therethrough. The ultrasonic transducer assembly is sealed within the distal tubular end and is thereby isolated from the adverse corrosive and thermal effects of the ionic medium.

WO 01/68173 A3

INTERNATIONAL SEARCH REPORT

ternational Application No
PCT/EP 01/02741

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 6 004 269 A (ABELE JOHN E ET AL) 21 December 1999 (1999-12-21) abstract	1
A	US 5 840 031 A (CROWLEY ROBERT J) 24 November 1998 (1998-11-24) abstract	1
A	WO 98 58681 A (EP TECHNOLOGIES) 30 December 1998 (1998-12-30)	
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☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
26 September 2001	04/10/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Papone, F

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